Remarks/Arguments

The Examiner has rejected Claims 7, 10, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villani (4,659,716) in view of Hansen (5,658,899) and/or Strupczewski (4,954,503) and/or Congy (5,290,951).

In response, applicants have cancelled Claims 7, 10, and 13.

The Examiner stated that Claims 8, 9, 11, 12, 14, 15 are allowed for reasons of record, and process Claims 16-21, if amended to depend on the allowable claims 8, 9 would also be allowable.

In response, applicants have amended Claims 16 and 17 to depend on Claim 8, and Claims 19 and 20 to depend on Claim 9.

Applicants have submitted herewith a supplemental information disclosure statement listing a reference which was cited in the International Search Report dated November 28, 2003. The reference is WO 02/42290, a copy of which is included herewith.

WO 02/42290 states on page 2, lines 1-5, of the PCT published application that Hungarian Patent No. 194 864 (U.S. 4,659,716, Villani) states that salts can be formed from desloratadine with pharmaceutically acceptable acids: hydrochloric acid, methanesulfonic acid, sulfuric acid, acetic acid, maleic acid, fumaric acid, and phosphoric acid. WO 02/42290 describes the following desloratidine salts: desloratidine disulfate, desloratidine dihydrogen chloride, desloratidine dihydrogen bromide, and desloratidine hemisulfate. It is noted that in Example 5 of WO 02/42290, a salt of deloratadine is prepared using maleic or fumaric acid, depending on ones' interpretation of the structure provided. As stated in the table on page 8, this desloratadine salt has a melting point of 169-171°C.

In contrast, applicants' polymorphic Forms 1 and 2 of desloratadine hemifumarate have a melting point, as determined by differential scanning colorimetry (DSC) of 224°C $\pm$ 2°C and 232°C $\pm$ 2°C, respectively, as claimed in applicants' Claims 16 and 19. Thus, the melting points of applicants' polymorphic Forms 1 and 2 of desloratadine hemifumarate are significantly different than the melting point of the desloratadine salt prepared according to WO 02/42290.

In addition, neither Villani, as noted by the Examiner, nor WO 02/42290 specifically describe polymorphic desloratadine hemifumarate, as claimed by applicants. Applicants' Claims 8 and 9 describe polymorphic Forms 1 and 2 of desloratadine hemifumarate by their respective powder X-ray diffraction patterns. Thus, WO 02/42290 does not teach or suggest applicants' polymorphic desloratadine hemifumarate, as claimed.

It is requested that the Examiner enter the above amendments, and pass the case to issue.

Respectfully submitted,

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